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| APPLICATION NO.                  | FILING DATE         | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|----------------------------------|---------------------|----------------------|-------------------------|------------------|
| 09/647,475                       | 08/20/2001          | Olav K. Lyngberg     | 110.00810101            | 7111             |
| 26813 75                         | 590 12/02/2003      |                      | EXAMINER                |                  |
| MUETING, RAASCH & GEBHARDT, P.A. |                     |                      | CHEU, CHANGHWA J        |                  |
| P.O. BOX 5814                    | 415<br>(S. MN 55458 |                      | ART UNIT PAPER NUMBER   |                  |
| MINNEALOE                        |                     |                      | 1641                    | 19               |
|                                  |                     |                      | DATE MAILED: 12/02/2003 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| •  |  | Application No.  | Applicant(s)   |  |  |  |
|--|--|--|--|--|--|--|
| Office Action Summary  |  | 09/647,475   | LYNGBERG ET AL.  |  |  |  |
|  |  | Examiner   | Art Unit   |  |  |  |
|  |  | Jacob Cheu   | 1641   |  |  |  |
|  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |  |  |  |
| THE - Exte after - If the - If NC - Failu - Any  | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing adparent term adjustment. See 37 CFR 1.704(b).   | 136(a). In no event, however, may a reply be the statutory minimum of thirty (30) do will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDON  | timely filed  ays will be considered timely.  m the mailing date of this communication.  IED (35 U.S.C. § 133).  |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 16 S   | September 2003.  |  |  |  |  |
| 2a) <u></u> ☐  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |  |  |  |  |  |
| 3)□  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |  |  |  |  |
| Disposit   | on of Claims   |  |  |  |  |  |
| 5)□<br>6)⊠<br>7)□  | Claim(s) 1-24,48 and 100-108 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) 1-24,48 and 100-108 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election requirement.   |  |  |  |  |  |
|  | on Papers  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |  |  |  |  |  |  |
| 10)  | The drawing(s) filed on is/are: a) acc   | cepted or b) objected to by the  | Examiner.  |  |  |  |
|  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |  |  |  |
|  | Replacement drawing sheet(s) including the correct   | •  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |  |  |  |  |  |  |
| •  | ınder 35 U.S.C. §§ 119 and 120   |  |  |  |  |  |
| * 5<br>13)   | Acknowledgment is made of a claim for foreig All b) Some * c) None of:  1. Certified copies of the priority document Certified copies of the priority document None of:  2. Certified copies of the priority document None of the certified copies of the priority document None of the None of the Priority document None of the No | ts have been received. Its have been received in Applica ority documents have been received (PCT Rule 17.2(a)). In of the certified copies not received priority under 35 U.S.C. § 119 st sentence of the specification of the covisional application has been reside priority under 35 U.S.C. §§ 12 | tion No  yed in this National Stage  yed.  (e) (to a provisional application)  or in an Application Data Sheet.  sceived.  0 and/or 121 since a specific |  |  |  |
| Attachmen  | t(s)<br>e of References Cited (PTO-892)  | A) Intension Summer  | y (PTO-413) Paper No(s)  |  |  |  |
| 2) 🔲 Notic   | e of References Clied (PTO-692) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) 5  | 5) Notice of Informal  | Patent Application (PTO-152)   |  |  |  |

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#### **DETAILED ACTION**

1. Applicant's amendment filed on September 16, 2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

- 1. Claim 25-47, 49-99 are cancelled.
- 2. Claims 100-108 are added to the instant application.
- 3. Currently, claims 1-24, 48, 100-108 are pending for examination.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1, 2, 6, 7, 9-13, 15, 18, 22, 48, 100-105, 107-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Thiagarajan et al. (European Federation of Biotechnology, 1995, page 304-312).

Thiagarajan et al. teach immobilizing viable bacterial on biofilm for measuring oxygen consumption. (See Introduction) Thiagarajan et al. teach mixing E. Coli with non-toxic latex polymers and to form the bacteria/latex biostructure. (page 306, last paragraph) The biostructure is desiccation tolerant since the process involving dryness. (page 308, first paragraph) The device also containing a non-porous latex derived material for the coating plates. (See Figure 2) The device can detect oxygen consumption by E. Coli and inherently contains elements of transmitter and detector. (See Figures 6-8)

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4. Claims 1, 4-10, 14-15, 18-20, are rejected under 35 U.S.C. 102(b) as being anticipated by Cantwell et al. (EP 0288203)

Cantwell et al. teach a composite biological composition comprising immobilizing metabolically active cells on the nonporous polymers, e.g. latex. (See abstract) Cantwell et al. teach that admixtures cells with the nonporous latex to form agglomerates resulting in intertwining or imbedding cells with the polymers. (page 3- page 4) The cells are selected from bacteria and fungi. (page 4, third paragraph) Bacteria containing certain detectable enzyme, such ascatalase, oxygenase, dehalogenase, could be inherently genetically manipulated into different strain. (page 6, example 1; claim 1-8) The cells and each polymer were used at a concentration of 10% w/v. (page 6-8) The immobilizing cells on the latex is by several forces, including cross-link. (page 2, line 25-30) The composition is inherently desiccation tolerant because the composition is in a colloidally stable condition when mixing with cells, and using polyvinylidene chloride polymer which intends to be a water barrier. (page 4, line 45-57)

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 5. Claims 1-3, 6-22, 48, 100-108 are rejected under 35 U.S.C. 102(a) as being anticipated by Nova et al. (US 5751629).

Nova et al. teach a composition for molecular tracking and identification comprising matrices where the matrices are latex polymers and joining or linking to phage, eukaryotic cells, prokaryotic cells or bacteria which are metabolic active biological organisms. (Col. 6, line 15-36; claims 1-4) The linking process can be done with various means, including disulfide linkage or thioether bonds. (Col. 20, line, 54-65) The composition contains transmitter and detector for signal detection depending on various needs, including identifying nucleic acid, peptides or proteins. (Col. 5, line 12-30; Figure 6-7) The composition taught by Nova et al. also includes non-porous latex channel or

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microtiter plates. (see Figure 7 and Col. 6, line 20-35) Nova et al. also teach using mass spectrometry, thin layer chromatography, gel electrophoresis, or HPLC to purify samples. Thus, the composition of Nova et al. can be adapted to the aforementioned equipments and include electrodes and wires. (Col. 14, line 24-35) Nova et al. also teach using the composition to simultaneously determine large numbers of analytes in any format, e.g. phage library, because each known analyte data have been recorded and stored in the system. (Col. 34, line 2-15; claims 1-8)

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova in view of Wagner et al. (US 6475808)

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Nova et al. reference has been discussed but does not explicitly teach the thickness of the biostructure. Wagner et al. teach an array of screening of biomolecular activity where biomolecules specific binding partner, e.g. antibodies, are immobilized on the microarray device. (See Figures 1-3) Wagner et al. teach the thickness of the solid support for immobilizing biomolecules are in range of 50 to 500 nm. (Col. 11, line 50-60) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Nova et al. with method of manufacturing microarray solid support as taught by Wagner et al. to have a thinner solid support for coating biomolecules since it is economical and convenient for the purposes of mass screening.

## Response to Applicant's Arguments

- 9. Applicant's arguments with respect to claims 1-24, 48 have been considered but are moot in view of the new ground(s) of rejection.
- 10. Examiner withdraws the rejection of *public use* under 35 U.S.C. 102 (a) in light of the amended claim.
- 11. Examiner withdraws the rejection under 35 U.S.C. 102 (a) anticipated by Lyngberg et al. (J. Ind. Microbiol. Biotech. (1999) 23: 668-676) in light of applicant's submission of provisional application document.

#### Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

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November 19, 2003

LONG V. LE

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

11/29/03